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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,907	03/09/2004	Duran Yetkinler	SKEL-012CIP	3390
24353	7590	02/02/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/797,907		YETKINLER ET AL.	
	Examiner		Art Unit	
	Anu Ramana		3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/2/05; 12/13/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 21, 2005 has been entered.

Claim Objections

Claim 36 is objected to because of the following informalities. In line 2, insert - - to - - after "force" and before "said (first occurrence)." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

In claim 39, the limitation, "from about 0.1-5 to about 100,000 Hz" renders the claim vague and indefinite because it is unclear what range the Applicant is trying to claim. The starting point of the claimed range is unclear. For purposes of examination, the range is assumed to be from about 0.1 to about 100,000 Hz. Appropriate correction or clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-38, 40-41 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Constantz et al. (US 6,083,229).

Constantz et al. disclose a method of introducing calcium phosphate cement for orthopedic applications including the steps of: positioning a needle or "hardware device" in a cancellous bone region or "target bone site" of a compromised vertebral body; and delivering bone cement to the target bone site by vibrating the needle (col. 25, lines 38-59, col. 27, lines 11-57, col. 28, lines 15-67, col. 29 and col. 30, lines 1-38).

Regarding claim 37, Constantz et al. disclose that prior to the step of introducing the cement, the vertebral body may be reduced (col. 26, lines 16-42).

Regarding claim 40, Constantz et al. disclose that cement delivery to the cancellous bone region can be enhanced by the application of energy, for e.g., vibrating the cement delivery means, instead of the use of pressure, interpreted by the Examiner as "without the use of substantial pressure."

Regarding claim 41, Constantz et al. disclose the use of vibration to perfuse cement to a target bone site. Thus, stopping vibration would "substantially stop" penetration of cement to the target bone site except for penetration of cement by infiltration.

Claims 33-36, 38-39 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Olson, Jr. et al. (US 2004/0024410 A1).

Olson, Jr. et al. disclose a method of introducing a cement composition into a target bone site in the cancellous region of a compromised vertebral body for treatment of a fracture including the steps of: positioning a guidewire 14 or "hardware device" at a

target bone site; and delivering the cement composition in conjunction with vibration by mechanically coupling a vibration device 100 to an end of guidewire 14 (Figs. 3 and 11, paras [0015], [0045], [0057]-[0059] and [0075]-[0076]).

Regarding claim 35, Olson, Jr. et al. disclose delivering cement to a target site by disposing a second tubular element or "cement composition introduction element" within the tubular element 12 (para [0045], lines 22-26).

Regarding claim 39, Olson, Jr. et al. disclose the frequency of vibration to be between 1/sec to 100/sec, i.e., 1 to 100 Hz (para [0058]). It is noted that a specific example in the prior art, which is within a claimed range, anticipates the range. MPEP 2131.03.

Claims 48, 51 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Sproul (US 6,832,988).

Sproul discloses a kit including: a cannula or "cement composition introduction element"; an ultrasonic probe or "vibratory element"; and a pedicle screw or wire or "implantable hardware device" (col. 2, lines 57-60, col. 4, lines 16-67, col. 5, lines 1-7 and col. 8, lines 43-50).

Regarding the limitation, "for vibrating said cement at some point during its preparation or use," it is noted that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-34, 37-38 and 42-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karpman et al. (US 6,214,012) in view of Bakels (US 4,787,751).

Karpman et al. disclose the method steps of: positioning a hardware device such as a cannulated screw 30 in conjunction with any number of conventional fixation devices such as wires, plates, rods at a target bone site including cancellous bone; and delivering cement to the target bone site by a cement gun for internal fixation following fracture reduction (Figs. 3 and 4, col. 5, lines 5-67, col. 7, lines 5-29 and col. 9, lines 24-54).

Karpman et al. disclose all elements of the claimed invention except for delivering cement in conjunction or "association" with vibration.

Bakels teaches reduction of porosity and improving the fatigue strength of bone cement by vibrating a cement gun cartridge prior to placing the cartridge in a cement gun for delivery of cement to a desired operating area (col. 1, lines 6-43).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have vibrated the bone cement cartridge in the Karpman et al. cement gun, as taught by Bakels, prior to introduction of cement to the target bone site in order to reduce the porosity of the cement and improve its fatigue strength.

Regarding claim 46, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a calcium phosphate cement in the method of the combination of Karpman et al. and Bakels, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein orthopedic fixation, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

The method steps of claims 33-34, 37-38 and 42-46 are rendered obvious by the above discussion.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,083,229) in view of Olson, Jr. et al. (US 2004/0024410 A1).

Constantz et al. disclose all elements of the claimed invention except for vibrating the cement delivery means with a frequency in a range of about 0.1 to about 100,000 Hz.

Olson, Jr. et al. teach vibrating a cement delivery device at a frequency in a range of 1 to 200 Hz for compaction of the cement. Olson, Jr. et al. also teach that other ranges of frequency may be used depending on factors such as composition, consistency, density, etc. of the cement (paras [0056]-[0059]).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have vibrated the Constantz et al. cement delivery means, as taught by Olson, Jr. et al., to compact the cement.

The combination of Constantz et al. and Olson, Jr. et al., discloses the claimed invention except for vibrations having a frequency in a range of about 0.1 to 100,000 Hz. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized vibrations having a frequency in a range of about 0.1 to 100,000 Hz to vibrate the cement delivery means in the method of the combination of Constantz et al. and Olson, Jr. et al., since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olson, Jr. et al. (US 2004/0024410 A1) in view of Constantz et al. (US 6,083,229).

Olson, Jr. et al. disclose all elements of the claimed invention except for: a calcium phosphate cement composition.

Constantz et al. teach a calcium phosphate bone cement for treatment of compromised vertebral bodies (col. 25, lines 38-67, cols. 26 and 27 and col. 28, lines 1-13).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a calcium phosphate cement, as taught by Constantz et al., in the method of Olson, Jr. et al., since it was known in the art to utilize

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a calcium phosphate cement for the purpose of treatment of compromised vertebral bodies.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olson, Jr. et al. (US 2004/0024410 A1) in view of Bakels et al. (US 4,787,751).

Olson, Jr. et al. disclose all elements of the claimed invention except for: the step of preparing a cement composition in conjunction with vibration.

Bakels et al. teach preparation of bone cement utilizing vibration to deaerate the cement prior to its introduction to a desired operating area in order to increase the fatigue strength of the cement (col. 1, lines 5-8 and lines 24-43, col. 2, lines 30-68, col. 3, lines 1-62 and col. 5, lines 3-16).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized vibration during preparation of bone cement, as taught by Bakels et al., to reduce porosity and increase the fatigue strength of the cement.

The method steps of claim 47 are rendered obvious by the above discussion.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sproul (US 6,832,988) in view of Constantz et al. (US 6,083,229).

Sproul discloses a kit including a cement composition introduction element, a vibratory element, an implantable hardware device, and pouches or solutions for tissue augmentation (col. 2, lines 57-60 and col. 8, lines 43-50).

Sproul discloses all elements of the claimed invention except for an explicit reference to providing a cement composition as part of his kit.

Constantz et al. teach providing a mixing device and storage means for a two-component cement in a kit for use in applications where calcium phosphate cements are employed (col. 25, lines 15-29).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a cement composition as part of the Sproul kit, as

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taught by Constantz et al., for storage and mixing of the cement composition prior to delivery at the target bone site.

Claims 50 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sproul (US 6,832,988) in view of Karpman et al. (US 6,214,012).

Sproul discloses that his kit can be produced in various sizes and combinations depending on the procedures to be accomplished (col. 8, lines 43-50). See previous discussion for claim 48.

Sproul discloses all elements of the claimed invention except for: a hardware device such as a plate or a cannulated screw.

Karpman et al. teach the use of cannulated screws and plates in internal fixation of fractures for the purpose of holding bone (col. 5, lines 62-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided plates or cannulated screws in the Sproul kit, as taught by Karpman et al., for purposes of internal fixation of a fractured bone.

Response to Arguments

Applicant's presented new claims 33-53 in the Request for Continued Examination filed on November 21, 2005. No arguments were presented with respect to the new claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR
January 31, 2006

Annabelle Ramana
AU 3733